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No. _____

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1993

MUTUAL OF OMAHA LIFE INSURANCE COMPANY,

Petitioner,

v.

MARY P. DAHL-EIMERS,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

PETITION FOR A WRIT CERTIORARI

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QUESTIONS PRESENTED

1. Must a Federal Court of Appeals which has issued its panel opinion in an appeal from an order denying a motion for a preliminary injunction, vacate its opinion and dismiss the appeal upon learning that changed circumstances rendered moot the motion for a preliminary injunction prior to the issuance of its panel opinion?

2. May a Federal Court of Appeals assert jurisdiction to resolve questions of law raised in an interlocutory appeal certified pursuant to 28 U.S.C. § 1292(b), when the order appealed from was rendered moot by changed circumstances occurring prior to the issuance of the court's panel opinion?

LIST OF PARTIES

All parties to the proceeding below appear in the caption.[1]

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[1] Pursuant to Supreme Court Rule 29.1, Petitioner Mutual of Omaha Insurance Company identifies the following subsidiaries and affiliates: Adjustment Services, Inc., ARD-RICH Realty Corporation, Companion Life Insurance Company, Deco Realty Inc., Exclusive Healthcare, Inc., Exclusive Healthcare of Colorado, Inc., Health America/Capital Care, Inc., Kirkpatrick, Pettis, Smith, Polian Inc., Omaha Capital Corporation, Mutual Asset Management Company, Mutual of Omaha Fund Management Company, Mutual of Omaha International Ltd., Mutual of Omaha Marketing Corporation, Mutual Plan Administration, Inc., Omaha Financial Life Insurance Company, The Omaha Indemnity Company, Omaha Property and Casualty Insurance Company, Omex Realty Inc., Tele-Trip Company Inc., UB realty Inc., United of Omaha Life Insurance Company, United World Life Insurance Company.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

LIST OF PARTIES ii

TABLE OF AUTHORITIES v

OPINIONS BELOW 1

JURISDICTION 2

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED 2

STATEMENT OF THE CASE 3

A. *The Original Complaint* 3

B. *The District Court Decision* 4

C. *The Decision of the Panel on the Preliminary Injunction* 5

D. *The Change of Circumstances* 6

E. *The Motion to Vacate* 12

REASONS FOR GRANTING THE WRIT 13

I. THE ELEVENTH CIRCUIT'S EXERCISE OF JURISDICTION OVER AN APPEAL FROM A MOTION FOR A PRELIMINARY INJUNCTION RENDERED MOOT BY CHANGED CIRCUMSTANCES OCCURRING IN ADVANCE OF THE PANEL'S OPINION CONFLICTS DIRECTLY WITH DECISIONS OF THIS COURT 13

A. *Changed Circumstances Mooted Plaintiff's Request for a Preliminary Injunction* 13

TABLE OF CONTENTS – Continued

Page

B. *When Changed Circumstances Mooted the Motion for a Preliminary Injunction, the Eleventh Circuit Was Left With No Basis for Continuing Jurisdiction* 20

C. *The Proper Disposition is to Vacate Prior Opinions and Dismiss the Appeal* 26

II. THIS CASE PRESENTS AN IMPORTANT JURISDICTIONAL QUESTION OVER WHICH THE COURT SHOULD EXERCISE ITS SUPERVISORY POWERS 29

CONCLUSION 30

TABLE OF AUTHORITIES

Page

CASES

Adkinson v. International Harvester Company, 975 F.2d 208 (5th Cir. 1992) 25

Aetna Life Insurance Co. v. Haworth, 300 U.S. 227 (1937) 14

Bumpus v. Clark, 702 F.2d 826 (9th Cir. 1983) 27

Clark v. K-Mart Corporation, 979 F.2d 965 (3rd Cir. 1992) 14, 15

Clarke v. United States, 915 F.2d 699 (D.C. Cir. 1990) 27

Dahl-Eimers v. Mutual of Omaha Life Insurance Co., 812 F.Supp. 1193 (N.D.Fla. 1992) 4, 5, 10, 18

Dahl-Eimers v. Mutual of Omaha Life Insurance Co., 986 F.2d 1379 (11th Cir. 1993) 6, 20

DeFunis v. Odergaard, 416 U.S. 312 (1974) 14

Dillon v. Alleghany Corp., 111 S.Ct. 1383 (1991) 27

Edwardsville National Bank & Trust Co. v. Marion Laboratories, Inc., 808 F.2d 648 (7th Cir. 1987) 26

Honig v. Doe, 484 U.S. 305 (1988) 16

Honig v. Students of the California School for the Blind, 471 U.S. 148 (1985) 13, 22

Independent Union of Flight Attendants v. Pan American World Airways, Inc., 966 F.2d 457 (9th Cir. 1992) 27

Ivy Club v. Edwards, 943 F.2d 270 (3rd Cir. 1991), *cert. denied*, 112 S.Ct. 1282 (1992) 25

Lewis v. Continental Bank Corp., 494 U.S. 472 (1990) 13, 14, 16, 19

TABLE OF AUTHORITIES – Continued

Page

Miller v. Bolger, 802 F.2d 660 (3rd Cir. 1986) 26

Murphy v. Hunt, 455 U.S. 478 (1982) 19

North Carolina v. Rice, 404 U.S. 244 (1971) 13, 14

Ray v. American National Red Cross, 921 F.2d 324 (D.D.C. 1990) 25, 26

Schnitker v. Blue Cross Blue Shield, 787 F.Supp. 903 (D. Neb. 1991) 16

Sivley v. Soler, 113 S.Ct. 454 (1992) 27

Steffel v. Thompson, 415 U.S. 452 (1974) 14

Stewart v. Southern Railroad Co., 315 U.S. 784 (1942) 13, 27

Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747 (1986) 22

United States v. Munsingwear, 340 U.S. 104 (1950) 12, 13, 26, 27

United States v. Stanley, 483 U.S. 669 (1987)... 24, 25, 26

University of Texas v. Camenisch, 451 U.S. 390 (1981) 13, 20, 21, 22

Warth v. Seldin, 422 U.S. 490 (1975) 13

Weinstein v. Bradford, 423 U.S. 147 (1975) 16, 19

Yellow Freight System, Inc. v. United States, 113 S.Ct. 31 (1992) 27

CONSTITUTION AND STATUTUES

28 U.S.C. § 1254(1) 2

28 U.S.C. § 1292(b) ..... *passim*

TABLE OF AUTHORITIES – Continued

Page

MISCELLANEOUS

13A C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedure* § 3533.10 (1984)..... 28

R. Stern, E. Gressman, S. Shapiro, *Supreme Court Practice*, § 4.15 (B.N.A. 6th Ed. 1986)..... 29

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Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

PETITION FOR A WRIT CERTIORARI

The Petitioner, Mutual of Omaha Life Insurance Company ("Mutual"), respectfully requests that a writ of certiorari issue to review the order of the United States Court of Appeals for the Eleventh Circuit, entered in the above-entitled proceeding on June 21, 1993, denying Petitioner's Motion to Vacate Order and Dismiss Appeal as Moot.

OPINIONS BELOW

The Eleventh Circuit's order denying Petitioner's Motion to Vacate Order and Dismiss Appeal as Moot, entered June 21, 1993, is unreported, but appended to this Petition. The Eleventh Circuit's order on reconsideration of the June 21, 1993 order is unreported, but appended to

this Petition. The Eleventh Circuit's panel opinion on the merits of the appeal is reported at 986 F.2d 1379, and is reprinted in the Appendix to this Petition. The Order of the United States District Court for the Northern District of Florida denying Plaintiff's Motion for a Preliminary Injunction is reported at 812 F. Supp. 1193, and is reprinted in the Appendix to this Petition.

JURISDICTION

The order sought to be reviewed in this Petition was filed on June 21, 1993. Petitioner filed a Petition for Rehearing and Suggestion of Rehearing en banc in the Eleventh Circuit on July 9, 1993. The Eleventh Circuit construed the Petition as a motion for reconsideration of the June 21, 1993 order, and entered an opinion and order denying the motion on August 10, 1993. This Petition is filed within 90 days of the order of June 21, 1993.

The jurisdiction of this Court to review the order of the Eleventh Circuit is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III of the United States Constitution provides in relevant part:

> The judicial Power shall extend to all Cases, in Law and in Equity, arising under this Constitution, the Laws of the United States, and . . . to Controversies between citizens of different states. . . .

Section 1292(b) of Title 28 of the United States Code provides as follows:

> When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to

which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within 10 days after the entry of the order: Provided, however, that application for an appeal hereu .der shall not stay proceedings in the district court unless the district judge or the Court of Appeals or a judge thereof shall so order.

STATEMENT OF THE CASE

A. The Original Complaint.

The Plaintiff filed this action on July 2, 1992, in response to Mutual's decision, made June 10, 1992, to deny a request for preauthorization of health insurance benefits submitted on Plaintiff's behalf by the H. Lee Moffitt Cancer Center and Research Institute, Inc., in Tampa, Florida ("Moffitt"). The request from Moffitt sought preauthorization of benefits for Plaintiff's participation in a clinical trial evaluating a procedure known generally as high-dose chemotherapy with autologous bone marrow transplant ("HDC-ABMT"). HDC-ABMT involves the removal of a small portion of a cancer patient's own ("autologous") bone marrow, followed by the administration of chemotherapy at several times the standard or conventional dose level, one which destroys the patient's remaining bone marrow. After the administration of the high-dose chemotherapy, the stored marrow components are reinfused into the patient. HDC-ABMT is currently being tested in medical research facilities as a

means to overcome chemotherapy dose limitations relating to bone marrow destruction, and theoretically to improve chemotherapeutic treatment in a variety of solid tumor cancers, including breast cancer.

Mutual denied the Moffitt preauthorization request in reliance upon the applicable policy's defined scope of covered expenses. The Mutual policy covers only procedures which are "medically necessary", a term defined to omit procedures not appropriate and consistent with the diagnosis in accord with accepted standards of community practice; those considered experimental; or those which could have been omitted without adversely affecting the insured's condition or quality of care.

In the Complaint, Plaintiff alleged that she desired to immediately undergo HDC-ABMT at Moffitt under a specific treatment protocol known in shorthand form as the "ICE" protocol. Plaintiff claimed that time was of the essence, and that grave medical consequences would result from any delay. With the complaint, Plaintiff filed a motion for a preliminary injunction, asking the district court to immediately compel Mutual to preauthorize the requested benefits. Plaintiff requested and received expedited consideration of the motion in the district court. A hearing on the motion was held on July 20, 1992, eighteen days after the filing of Plaintiff's complaint.

B. The District Court Decision.

Nine days later, on July 29, 1992, the district court entered an Order and Memorandum Opinion denying the motion, finding that Plaintiff had failed to demonstrate a substantial likelihood of success on the merits of her claim. *Dahl-Eimers v. Mutual of Omaha Life Insurance Co.*, 812 F.Supp. 1193 (N.D.Fla. 1992). The court reached what it termed the "inescapable conclusion" that the procedure proposed for Plaintiff by Moffitt is experimental, and

therefore outside of the policy's coverage. *Id.* at 1197. The court reviewed the status of medical research evaluating HDC-ABMT in breast cancer, the federal regulatory requirements imposed upon medical experimentation in the United States, and the particular protocol and informed consent documents applicable to the clinical trial at Moffitt in which Plaintiff sought to participate. The court found that there was "no doubt about the nature of the [Moffitt] study. . . . Whether the ICE combination of drugs has a beneficial – or deleterious – effect upon breast cancer that has progressed to stage IV is simply not known. That is, understandably, why the Moffitt center desires to enroll the Plaintiff in its study." *Id.* at 1198. Finding the procedure experimental and therefore not covered under the Mutual policy, the Court did not find it necessary to discuss the other portions of the policy definition of "medically necessary."

The ultimate conclusion of the District Court was that Plaintiff did not demonstrate "a substantial likelihood of prevailing on the merits of this case," and that the prerequisites of a motion for a preliminary injunction were therefore unsatisfied. *Id.* at 1198. The only substantive ruling contained in the district court's order was its denial of Plaintiff's motion for a preliminary injunction.

In the last paragraph of its opinion, the district court recited the requirements of 28 U.S.C. § 1292(b), certifying that the order "involves a controlling question of law as to which there is substantial ground for difference of opinion, and an immediate appeal may materially advance the ultimate determination of the litigation. Time is also of the essence." *Id.* at 1198.

C. The Decision of the Panel on the Preliminary Injunction.

Given the district court's certification, the Plaintiff sought and obtained leave to file an interlocutory appeal

to the Eleventh Circuit under section 1292(b). The order appealed from was the only order entered in the case by the district court – its decision denying the motion for a preliminary injunction.

After briefing and argument, the Eleventh Circuit filed its opinion on March 9, 1993, ruling only on a narrow question of law, concluding that the policy language upon which the district court relied is ambiguous. *Dahl-Eimers v. Mutual of Omaha Life Insurance Co.*, 986 F.2d 1379 (11th Cir. 1993). In its opinion, the panel identified the issue presented as whether "the district court correctly denied Plaintiff-Appellant Mary P. Dahl-Eimers' application for a preliminary injunction." *Id.* at 1380. The Court characterized its inquiry as whether the district court's determination regarding Plaintiff's likelihood of success on the merits was correct. *Id.* The relief granted in the panel opinion was focused particularly upon the preliminary injunction, as the Court remanded the case to the district court for a new determination regarding whether there exists "a substantial likelihood that [Plaintiff] will prevail on the merits" in light of the panel's decision. *Id.* at 1384.

D. The Change of Circumstances.

Over the several months in which the appeal was pending before the Eleventh Circuit, Plaintiff continued to receive medical care for her cancer. In the fall of 1992, she received two courses of conventional dose chemotherapy. (Dahl-Eimers Dep. 17:12-22; R. Eimers Dep. 7:15-8:2).[2] Her physicians also prescribed a course of

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[2] References are to the depositions and affidavits submitted to the Eleventh Circuit in support of Petitioner's Motion to Vacate. The deposition of Plaintiff and her husband were taken April 23, 1993.

radiation therapy, consisting of thirteen separate treatments, which continued through January 4, 1993. (R. Eimers Dep. 8:3-9). Then, from January 5 through 27, 1993, Plaintiff received treatment at the Contreras Clinic in Tijuana, Mexico, consisting of Laetrile therapy, additional radiation therapy, and a specialized diet and dietary supplement regimen. (Dahl-Eimers Dep. 24:16-25:24; 28:14-29:5; R. Eimers Dep. 8:13-17).

Fortunately, Plaintiff's condition improved substantially following Plaintiff's return from Mexico. Within two weeks of completing the course of treatment in Mexico, Plaintiff no longer experienced pain, exhibited no clinical evidence of active disease, and blood tumor marker tests showed no evidence of disease progression. (Dahl-Eimers Dep. 29:15-31:14; 51:17-20). Plaintiff's physicians advised her that she was in remission, without evidence of active disease.

The Eleventh Circuit issued its opinion on March 9, 1993. After reviewing the opinion, Plaintiff's husband contacted each of Plaintiff's three treating physicians about the advisability of Plaintiff moving ahead with a bone marrow transplant. (R. Eimers Dep. 11:12-12:12; 16:11-16). According to the Plaintiff and her husband, each physician advised them not to go forward with HDC-ABMT.

> Q: [W]hat was [Dr. Vaughan's] response?
>
> A: His response was that as long as she is feeling good and there is no sign of active disease, because she has already had two more doses of chemotherapy, that he would wait until the cancer definitely had returned before we would go any further in this discussion.
>
> * * *
>
> Q: So the consensus of opinion among those three physicians was to wait?

A: Yes.

Q: And that ultimately has been your decision?

A: Yes.

(R. Eimers Dep. 12:25-13:6; 16:20-24. *See* R. Eimers Dep. 12:1315:16; Dahl-Eimers Dep. 8:3-9:16).

Thus, beginning approximately February 10, 1993, and continuing through all activity in the case before the Eleventh Circuit, Plaintiff had no intent or desire to undergo HDC-ABMT. Instead, Plaintiff decided that it was in her best interest to reconsider HDC-ABMT only if and when her disease recurs such that HDC-ABMT again becomes medically appropriate.

Q: Let me ask you this: As we sit here today, is it your intent to not go forward with the bone marrow transplant until such time as you have experienced some recurrence of your disease?

A: Yes.

Q: Is that based upon the advice and consultation of any physician?

A: Yes.

(Dahl-Eimers Dep. 33:20-34:1). Plaintiff's physicians have also indicated they have no way to predict when, if ever, her disease will again become active.

Q: Did he give you any indication of when that might be?

A: He doesn't have a crystal ball.

Q: He doesn't know?

A: Has no idea.

Q: Okay, all right.

A: How do they know when it's going to reoccur? They don't know.

(R. Eimers Dep. 13:7-14). In fact, it is not medically possible to predict at what point in time Plaintiff may experience a change in her symptoms, nor to predict what will

be the nature and scope of her disease if and when such a change occurs. (Herberman Aff. ¶ 16).

Plaintiff's intent is to enjoy her current good health, and upon the recurrence of her disease seek further advice from her physicians about how best to proceed. Whether that advice will be to pursue HDC-ABMT or some other procedure is unknown, as that advice will depend upon the nature of Plaintiff's condition at the time of relapse, the state of medical knowledge at that time, and the personal desires of the Plaintiff.

> Q: What is your intent if you should experience a reoccurrence of symptoms of your disease?
>
> A: What is my plan of action?
>
> Q: Intent with regard to therapy or your plan of action, that's a good term.
>
> A: It depends on what the diagnosis is.
>
> Q: I take it that if such an event occurs you will go see Dr. Chang?
>
> A: Yes.
>
> Q: And you will consult with him about a course of action?
>
> A: Yes.
>
> Q: And your understanding would be that that course of action would be dependent upon what those symptoms were and what –
>
> A: Right, right.
>
> Q: – was the nature of your disease?
>
> A: Exactly.
>
> Q: As you sit here today do you consider one of the possibilities at that point in time to be a bone marrow transplant?
>
> A: Yes.

(Dahl-Eimers Dep. 42:5-43:1. *See* Herberman Aff. ¶ 16).

In addition, Plaintiff has now decided that she may not want to receive the particular form of HDC-ABMT offered at Moffitt, described in the district court's opinion as the "ICE Protocol." *See Dahl-Eimers*, 812 F.Supp. at 1196-97. Instead, if and when she reconsiders HDC-ABMT, Plaintiff intends to evaluate protocols offered at several other research facilities throughout the country, including the University of Alabama at Birmingham, Sloan-Kettering Hospital, Dana Farber Cancer Institute, Fred Hutchinson Cancer Research Center, and the M. D. Andersen Tumor Center.

> Q: If that possibility comes to fruition, have you made a decision as of today's date as to where you will get that bone marrow transplant?
>
> A: Have I made a decision?
>
> Q: Yes.
>
> A: No.
>
> * * *
>
> Q: All right, that listing of six institutions that I just mentioned, is that a complete listing of the institutions that you have considered for a bone marrow transplant?
>
> A: No, I don't – we really haven't gotten into that yet.
>
> Q: Okay.
>
> A: To me that's like another issue. That's not – until I knew if I was getting it, it wasn't worth looking at where you are going to have it exactly. I mean, originally we were going to the Moffitt Center. We did a lot of research to get to that point. It didn't seem to help much, so we don't want to waste a lot of time.

(Dahl-Eimers Dep. 43:2-7; 47:24-48:12).

Accordingly, it is only when HDC-ABMT again becomes a possible option that Plaintiff intends to decide

where to seek HDC-ABMT, and thus which particular protocol in which to try to participate. Each such institution has its own specific approach to HDC-ABMT, including differences in the chemotherapy drugs used, dosages, schedules, and other important factors. (Herberman Aff. ¶ 17). Moreover, each facility's program evolves with time, so that it is not possible to predict whether HDC-ABMT for breast cancer will be offered at any given facility at some unspecified future date, or if available, the form in which the procedure might be offered. (Herberman Aff. ¶ 17-19). Until the time of relapse, Plaintiff cannot know whether she will meet the rigid patient selection criteria contained within any given protocol, and thus whether she will be eligible to participate in any given protocol. (Dahl-Eimers Dep. 63:21-64:4; Herberman Aff. ¶ 20).

As a result of the change in Plaintiff's circumstances, she no longer possesses a present intent to seek HDC-ABMT at Moffitt under the ICE protocol, nor does she want or need the injunction originally requested. Plaintiff does not intend to even reconsider HDC-ABMT unless and until her current medical condition substantially changes. If and when that occurs, she will seek further medical advice and her course of treatment will depend on her diagnosis at that time. Even if HDC-ABMT is determined to be a proper avenue at that time, she intends to then explore multiple approaches to HDC-ABMT at a variety of facilities, for which she may or may not be medically eligible. Plaintiff herself recognized the impact of those changed circumstances upon her need for injunctive relief, voluntarily withdrawing the motion for a preliminary injunction in the district court on April 23, 1993.

E. The Motion to Vacate.

Mutual learned about the changed circumstances shortly after issuance of the panel opinion. Mutual promptly requested and completed additional discovery about those changed circumstances, and filed a Motion to Vacate Panel Opinion and Dismiss Appeal as Moot on April 29, 1993. In the motion, Mutual argued that the change of circumstances rendered moot Plaintiff's request for preliminary injunctive relief, that the events which gave rise to mootness occurred in advance of the Eleventh Circuit's panel opinion, and that in such circumstances the court is deprived of jurisdiction and compelled to dismiss the appeal and vacate the panel opinion. The motion was supported by the deposition testimony of Plaintiff and her husband, and an affidavit from Mutual's expert oncologist.

On June 21, 1993, the Eleventh Circuit issued a one paragraph order denying the motion without prejudice to the right of the parties to raise the issue before the district court. On July 9, 1993, Mutual filed a Petition for Rehearing and Suggestion of Rehearing En Banc relating to the jurisdictional issues, which was construed by the panel as a motion for reconsideration of its June 21, 1993 order. That motion was denied by the panel on August 10, 1993. This time, the panel issued a one page opinion stating that the case was not moot, and that vacatur of its initial opinion was not required because the appeal concerned a question of law certified under section 1292(b). The Court concluded it was not obligated to follow the rationale of *United States v. Munsingwear,* 340 U.S. 104 (1950), and declined to vacate its prior order or dismiss the appeal as moot.

REASONS FOR GRANTING THE WRIT

I. THE ELEVENTH CIRCUIT'S EXERCISE OF JURISDICTION OVER AN APPEAL FROM A MOTION FOR A PRELIMINARY INJUNCTION RENDERED MOOT BY CHANGED CIRCUMSTANCES OCCURRING IN ADVANCE OF THE PANEL'S OPINION CONFLICTS DIRECTLY WITH DECISIONS OF THIS COURT.

The Eleventh Circuit's refusal to recognize the absence of jurisdiction and vacate its judgment is directly contrary to decisions of this Court on three particular topics: (1) the constitutional requirement of an ongoing case or controversy at all stages of the litigation, *see Lewis v. Continental Bank Corp.*, 494 U.S. 472 (1990); *North Carolina v. Rice*, 404 U.S. 244 (1971); (2) jurisdictional limitations in an appeal from an order on a preliminary injunction, *see University of Texas v. Camenisch*, 451 U.S. 390 (1981); *Honig v. Students of the California School for the Blind*, 471 U.S. 148 (1985); and, (3) the appropriate disposition of an appeal when changed circumstances render moot the order appealed from, *see United States v. Munsingwear*, 340 U.S. 104 (1950); *Stewart v. Southern Railroad Co.*, 315 U.S. 784 (1942).

A. Changed Circumstances Mooted Plaintiff's Request for a Preliminary Injunction.

Concepts applicable to a federal court's exercise of jurisdiction are well settled. Under Article III, federal courts may adjudicate only actual, ongoing cases or controversies. *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477 (1990); *Warth v. Seldin*, 422 U.S. 490, 499 (1975). Federal courts may decide only those questions which affect the rights of the litigants in the case at issue. Article III confines federal court jurisdiction to "real and substantial controversies admitting of specific relief through a decree

of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 241 (1937). *See North Carolina v. Rice*, 404 U.S. 244, 246 (1971). The case or controversy requirement of Article III applies at all stages of the case. Thus, when intervening events render a case moot, destroying the interest of the parties to the adjudication, federal courts are prohibited from exercising continuing jurisdiction over the dispute. *Lewis*, 494 U.S. at 477-78; *DeFunis v. Odegaard*, 416 U.S. 312, 316 (1974); *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974).

Plaintiff's request for preliminary injunctive relief unquestionably became moot at the moment she no longer possessed a current intent to undergo HDC-ABMT under the ICE protocol at Moffitt. The relief requested in the motion, an order compelling Mutual to preauthorize medical benefits for Plaintiff's participation in the Moffitt clinical trial of HDC-ABMT, is no longer needed or desired by Plaintiff, and no order of any court on the motion could affect the rights of the parties. Given Plaintiff's decision to await a change in her medical condition, and the numerous uncertainties regarding whether HDC-ABMT may or may not be appropriate at that time, no action or inaction of Mutual precludes Plaintiff from obtaining benefits for the medical care she currently desires. In fact, Plaintiff acknowledged that she no longer desires the requested relief by withdrawing her motion for a preliminary injunction in the District Court. This case became moot at the time Plaintiff's medical circumstances improved, and her need passed for a court order compelling the payment of benefits for HDC-ABMT under the ICE protocol at Moffitt.

An analogous situation was presented to the Third Circuit in *Clark v. K-Mart Corporation*, 979 F.2d 965 (3rd

Cir. 1992). *Clark* involved an appeal from a preliminary injunction requiring K-Mart to provide benefits for plaintiff's participation in a clinical trial of HDC-ABMT for breast cancer. While the appeal was pending, K-Mart complied with the preliminary injunction and paid for the procedure. The Third Circuit found that the appeal from the order granting a preliminary injunction had become moot by the plaintiff's receipt of the procedure. The court explained that the only issue before it on appeal was the propriety of a preliminary injunction, and that K-Mart's compliance with the injunctive order resolved the controversy on that particular portion of the case. *Id.* at 967. The court found that there was no controversy remaining for it to decide regarding the particular issue on appeal – whether the district court properly granted the motion for a preliminary injunction. *Id.*

Though the Plaintiff here has not yet received the procedure, the same legal concept is applicable. In both this case and in *Clark*, the injunctive aspect of the case was rendered moot because the Plaintiff no longer could benefit from an order compelling payment for the procedure. The origin of that change in circumstances, whether receipt of the procedure or a medical improvement rendering the procedure no longer appropriate, is of no relevance. The determinative fact is that the Plaintiff no longer desires or needs the injunctive relief requested.

Further, this case is not saved from mootness by the often cited but rarely applied exception for cases "capable of repetition yet evading review". This Court has departed from the jurisdictional demands of the mootness doctrine only in those "exceptional situations" where two circumstances are simultaneously present and strictly satisfied: (1) the challenged action is of too short a duration to be fully litigated prior to its cessation; and (2)

there is a reasonable expectation that the same complaining party will be subject to the same action again. *Lewis*, 494 U.S. at 479; *Weinstein v. Bradford*, 423 U.S. 147, 149 (1975). The proper focus in addressing the exception is not upon whether the particular claimant has demonstrated that a recurrence of the same dispute is probable for him or her, but is instead upon whether the controversy in general is inherently capable of repetition, yet of such limited duration as to be incapable of judicial review. *Honig v. Doe*, 484 U.S. 305, 308 n.6 (1988). The circumstances of this case fail to meet either element of the exception.

First, there is nothing inherent about HDC-ABMT, and the available period of time in which patients with metastatic breast cancer may receive the procedure, which precludes meaningful litigation of coverage disputes. While in many cases decisions about coverage must be made quickly through expedited proceedings, meaningful and complete judicial review is not precluded by the inherent nature of the dispute. Plaintiff's own briefs throughout this case have referred to the numerous published decisions addressing insurance coverage for HDC-ABMT in a variety of circumstances, which demonstrate that judicial activity is not foreclosed by the duration of the dispute. *See, e.g., Schnitker v. Blue Cross Blue Shield*, 787 F.Supp. 903 (D. Neb. 1991). The circumstances which caused this particular case to become moot – the improvement of Plaintiff's medical condition, her chosen course of therapy, and her decision not to proceed with HDC-ABMT are unique to this case. If Plaintiff's circumstances again change and were Plaintiff then to decide to pursue HDC-ABMT, a new lawsuit could be filed and litigated in time to grant meaningful relief, if such relief

were appropriate under the facts existing at that time.[3] At best, the typical medical circumstances of those who seek HDC-ABMT require prompt adjudication of their claims. The need for such prompt adjudication does not mean that the case evades review, nor does it warrant the premature exercise of jurisdiction over facts which are wholly speculative and uncertain.

Similar difficulties exist regarding the second requirement. While Plaintiff contends that at some unknown point in the future she may again seek HDC-ABMT, the factual circumstances which will surround that presumed request for preauthorization of benefits are uncertain and entirely speculative. It is impossible to define or predict the factual circumstances of the future dispute which may arise, if any, and thus impossible to predict whether this same Plaintiff will again litigate this same controversy on similar facts. Factual contingencies exist in several crucial areas.

1. *The Course of Plaintiff's Health.* It is impossible to predict changes which may take place in Plaintiff's medical condition between now and the date she eventually decides to reconsider HDC-ABMT as a possible treatment option. Plaintiff's disease may progress such that HDC-ABMT is not appropriate, she may develop another illness in the interim, she may become ineligible for HDC ABMT through some unrelated cause, or she may be so

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[3] The need for an immediate decision will be tempered by waiting periods which research institutions like Moffitt impose upon those who desire to receive HDC-ABMT. For example, when Plaintiff initially sought a preliminary injunction, she could not have been admitted to Moffitt to receive the procedure, for, at a minimum, 60 to 90 days after qualifying to participate in the protocol (Dahl-Eimers Dep. 48:25-49:11).

fortunate as to remain in remission. Whatever may happen to Plaintiff's medical condition in the future is absolutely unpredictable, and the status of that condition is crucial to a determination of the appropriate form of medical care, and thus to the issues raised by her request for injunctive relief. *See* Herberman Affidavit at ¶ 16. No suggestion has been made by Plaintiff that the circumstances of her illness at the time of any future change can be predicted with any degree of reliability.

2. *Policy Terms.* If Plaintiff's circumstances do change, the terms of her insurance policy in force with Mutual, if any policy is in force at that time, may be different than the terms now in effect. A coverage dispute of this nature turns heavily upon the terms of the contract in effect at the time of the claim, which in this case is unknown.

3. *Selection of Research Institution and Form of Treatment.* Plaintiff has indicated that she intends to consider at least five different research hospitals if she is advised to again explore HDC-ABMT, each of which offers a different form of the procedure under a unique, changing protocol. As described by the district court, the particular regimen of chemotherapy drugs and manner of administration of those drugs in any given protocol is an important factor in evaluating a dispute of this nature. For example, the Moffitt protocol in place at the time of Plaintiff's initial request included "dose-escalation" features in a phase I clinical trial, the earliest stage of clinical research on human subjects. *Dahl-Eimers,* 812 F.Supp. at 1196. Unless and until Plaintiff chooses a protocol in which to participate, and is declared at least potentially eligible, it would be impossible for any court to determine the characteristics of the particular form of HDC ABMT at issue. Further, research institutions continually

change and update research protocols to reflect new findings, thus the particular protocol which may be in place at any of the five institutions Plaintiff plans to investigate also cannot be predicted.

4. *Status of Research Efforts.* As is also apparent, the medical research community is actively and aggressively evaluating HDC-ABMT for metastatic breast cancer. Additional findings and conclusions may be available before Plaintiff again desires to undergo the procedure, which could weigh heavily in the inquiry one way or the other. The medical community may reach important conclusions about the efficacy of the procedure, or the lack thereof, which could entirely alleviate the need for this litigation.

These questions can be answered now only through guesswork and speculation. Each is an integral part of an analysis of the issues presented. Until those facts are definitively resolved, the exercise of jurisdiction by any court would amount to nothing more than the rendering of an advisory opinion on assumed facts which may or may not come to fruition. Thus, the likelihood that this same Plaintiff will again litigate this same controversy on similar facts is remote and hypothetical. A mere hypothesis or theoretical possibility of the same factual circumstances recurring is insufficient to satisfy the test stated in *Weinstein. See Lewis,* 494 U.S. at 479-80; *Murphy v. Hunt,* 455 U.S. 478, 482 (1982).

When Plaintiff's medical circumstances improved such that HDC-ABMT no longer was appropriate, the preliminary injunction she requested lost its value to her, and the issue was rendered moot. The nature of the dispute is not such that the case is saved from mootness because the same dispute is inherently likely to recur, yet evade review. The Eleventh Circuit's conclusion to the

contrary conflicts with long standing jurisdictional limitations imposed by Article III, and should not be permitted to stand.

B. When Changed Circumstances Mooted the Motion for a Preliminary Injunction, the Eleventh Circuit Was Left With No Basis for Continuing Jurisdiction.

The only issue on appeal before the Eleventh Circuit was the propriety of the District Court's refusal to issue a preliminary injunction. The Eleventh Circuit clearly recognized the limits of the issue before it in its panel opinion, correctly identifying the issue as "whether the District Court correctly denied Plaintiff's application for a preliminary injunction," and limiting its inquiry to Plaintiff's likelihood of success on the merits. *Dahl-Eimers*, 986 F.2d at 1380. The relief granted in the panel opinion was particularly focused upon the preliminary injunction. "Accordingly, we vacate the District Court's order denying Dahl-Eimers' application for a preliminary injunction and remand to the District Court to determine whether there is a substantial likelihood that she will prevail on the merits." *Id.* at 1384. Thus, the Eleventh Circuit properly did not address the merits of the Plaintiff's claims in its panel opinion, but merely one of several factors relevant to a consideration of the propriety of a preliminary injunction. Once the motion for a preliminary injunction became moot, there was no continuing basis upon which the appeal could continue.

The significant differences between an appeal on the merits and an appeal from an interlocutory order granting or denying a motion for preliminary injunction were explained by this Court in *University of Texas v. Camenisch*, 451 U.S. 390 (1981). In *Camenisch*, the Court discussed whether the existence of issues arising by the presence of

an injunction bond preserved an otherwise moot appeal from an order granting a preliminary injunction. Finding that no other issues could be considered once the preliminary injunction became moot, the Court examined the purpose of a preliminary injunction and its relationship to a decision on the merits.

> The purpose of a preliminary injunction is to preserve the relative positions of the parties until a trial on the merits can be held. Given this limited purpose, and given the haste that is often necessary if those positions are to be preserved, a preliminary injunction is customarily granted on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits. . . . In light of these considerations, it is generally inappropriate for a federal court at the preliminary injunction stage to give a final judgment on the merits.

Id. at 395.

The Court explained that there are significant procedural and substantive differences between a trial on the merits and a hearing on a motion for a preliminary injunction. As a result, a determination of Plaintiff's likelihood of success on the merits, often made within a few days of the filing of the lawsuit (18 in this case), cannot be equated with a decision on the merits. The two questions are independent and unique. Accordingly, when the injunctive aspects of an appeal from an order on a motion for preliminary injunction become moot, the appellate court is deprived of continuing jurisdiction to act on any other issue. In *Camenisch*, the Court specifically held that it is improper for an appellate court to reach or discuss the merits when the motion for a preliminary injunction, the only issue presented for review on appeal and the only issue upon which appellate jurisdiction could be premised, had become moot.

> In short, where a federal district court has granted a preliminary injunction, the parties generally will have had the benefit neither of a full opportunity to present their cases nor of a final judicial decision based on the actual merits of the controversy. Thus when the injunctive aspects of a case become moot on appeal of a preliminary injunction, any issue presented by an injunction bond can generally not be resolved on appeal, but must be resolved in a trial on the merits. . . . [I]t would be inappropriate for this Court to intimate any view on the merits of the lawsuit.

Id. at 1834-35. *See Honig v. Students of the California School for the Blind*, 471 U.S. 148, 149 (1985) (when appeal from an order on a preliminary injunction is moot, the court should remand the proceeding to the district court for a decision on other pending claims).[4]

This case presents a situation identical to that facing the Court in *Camenisch* and *Honig*. This case was before the Eleventh Circuit on an appeal only of the District Court's order addressing the propriety of a preliminary injunction, utilizing the various factors adopted by the Eleventh Circuit to evaluate such a request. No other issue was decided by the district court, or presented by the record on appeal. When the injunctive aspect of the case became moot, the Eleventh Circuit had no basis

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[4] The Court's decision in *Thornburgh v. American College of Obstetricians and Gynecologists*, 476 U.S. 747 (1986), is not to the contrary. There, the court identified a very limited circumstance in which a Court of Appeals may proceed to consider the merits in an appeal from a motion for a preliminary injunction. That rule could apply only if the injunctive aspects of the case remain justiciable. When the order appealed from is rendered moot, a Court of Appeals may not consider the merits under any circumstances.

upon which to assert continuing jurisdiction over the case. As a result, the Eleventh Circuit's issuance of its panel opinion and subsequent orders went beyond the bounds of its constitutionally circumscribed jurisdiction.[5]

In its order denying Petitioner's Motion for Rehearing, the Eleventh Circuit suggested that its jurisdiction continued because the appeal was certified under 28 U.S.C. § 1292(b), which permits interlocutory review of an order which addresses a controlling question of law as to which there is substantial ground for difference of opinion, when an immediate appeal would materially advance the litigation. The Court of Appeals concluded that because this appeal was certified on a question of law, and the legal question was not affected by the change of factual circumstances, it possessed continuing jurisdiction to decide that legal issue. That assertion of jurisdiction is contrary not only to the terms of the interlocutory appeal statute, but to this Court's decisions interpreting the statute.

The terms of section 1292(b) focus upon the appeal of "an order" entered by the District Court.

> When a district judge, in making in a civil action *an order* not otherwise appealable under this

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[5] Plaintiff's claim for declaratory relief remains pending in the district court. That claim has not yet been ruled upon by the district court, and was not before the Eleventh Circuit on appeal. It does not provide a justiciable claim before the Eleventh Circuit upon which it could continue to assert jurisdiction over the appeal. In addition, Plaintiff's request for declaratory relief is the subject of a pending motion to dismiss in the district court on grounds of mootness and ripeness, arising from the same change of circumstances which rendered moot the appeal on the preliminary injunction.

> section[6], shall be of the opinion that *such order* involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal *from the order* may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal in such action may thereupon, in its discretion, permit an appeal to be taken *from such order*, if application is made to it within 10 days after the entry of the order. . . .

Id. (emphasis added). As the statute states, an interlocutory appeal under section 1292(b) is from an order of the district court, not from a question of law divorced from district court action. While the legal question may be the reason for the certification and interlocutory appeal, the thing under review is the order, not the question.

This Court explained the difference in *United States v. Stanley*, 483 U.S. 669 (1987). In addressing the scope of jurisdiction under section 1292(b), the Court explained:

> An appeal under this statute is from the *certified order*, not from any other orders that may have been entered in the case. Even if the court of appeals' jurisdiction is not confined to the precise question certified by the lower court (because the statute brings the "order," not the question, before the Court), that jurisdiction *is* confined to the particular order appealed from.

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[6] Section 1292(b) is arguably not applicable here at all, as the statute confines the mechanism to those orders "not otherwise appealable under this section." Part (a) of section 1292 expressly permits an interlocutory appeal from an order refusing to issue an injunction. The district court's certification was not necessary to provide a basis for immediate appeal of its order.

Id. at 677 (emphasis in original). As a result, if the order appealed from becomes moot, section 1292(b) does not provide an independent basis upon which the court of appeals may continue to assert jurisdiction to decide the legal question at issue apart from the order, regardless of whether its decision may advance the ultimate termination of the litigation.

A similar issue was discussed by the Third Circuit in *Ivy Club v. Edwards*, 943 F.2d 270 (3rd Cir. 1991), *cert. denied*, 112 S.Ct. 1282 (1992). That case involved the appeal of an interlocutory order reopening a stayed proceeding pursuant to section 1292(b). Before the Third Circuit engaged in an analysis of the merits of the decision, it recognized its obligation to review the justiciability of the order, because the order had arguably been mooted by changed circumstances. In its discussion of that issue, the court recognized that section 1292(b) does not bring a legal issue before the court divorced from the district court's order in which that issue was decided. Citing *Stanley*, the Court explained:

> Because this Court has jurisdiction pursuant to 28 U.S.C. § 1292(b), the scope of appellate review extends only to questions of law raised by the order certified by the district court. However, it is the order that is appealable, and not the controlling question; and thus we may address any issue necessary to decide the appeal before us. We must necessarily decide the issue of mootness because this Court has a special obligation to satisfy itself of its own jurisdiction in every appeal presented to it.

Id. at 275-76 (citations omitted). *See Adkinson v. International Harvester Company*, 975 F.2d 208, 211 n.4 (5th Cir. 1992) ("On a certified interlocutory appeal under section 1292(b), we have jurisdiction to hear only questions that are material to the lower court's certified order."); *Ray v.*

American National Red Cross, 921 F.2d 324, 325 (D.C. Cir. 1990) ("The statute does not contemplate that a district court judge may simply certify a question without first deciding it."); *Edwardsville National Bank & Trust Co. v. Marion Laboratories, Inc.*, 808 F.2d 648, 650 (7th Cir. 1987) ("The question is the reason for the interlocutory appeal, but the thing under review is the order."); *Miller v. Bolger*, 802 F.2d 660, 666 (3rd Cir. 1986) ("Our review is of orders and not of isolated legal questions.").

Here, the order from which the appeal was taken was the district court's order addressing the Plaintiff's motion for a preliminary injunction. When that order became moot, section 1292(b) did not provide a basis upon which the Court of Appeals could continue to assert its jurisdiction over a question of law addressed in that order. Contrary to *Stanley*, the Eleventh Circuit found itself free to address the legal question apart from the existence of a justiciable controversy. Section 1292(b) does not permit such an extension of the Court's jurisdiction.

C. The Proper Disposition is to Vacate Prior Opinions and Dismiss the Appeal.

This is a case in which the Court of Appeals became aware, after its panel opinion was issued, that the order appealed from had become moot prior to the issuance of its opinion. In such circumstances, the proper disposition of the case is governed, like those issues discussed above, by established Supreme Court precedent.

When a federal appeal becomes moot in advance of decision, opinions issued in the case should be vacated and the appeal should be dismissed. The leading case discussing that established practice is *United States v. Munsingwear*, 340 U.S. 104 (1950). There, the Court explained that when a case becomes moot while awaiting review, prior opinions should be vacated to return the

legal relationships of the parties to the status existing prior to initiation of the suit, and to avoid the res judicata effects of an order which became jurisdictionally unreviewable. As the Court explained in *Munsingwear*, vacating a judgment "clears the path for future relitigation of the issues between the parties and eliminates a judgment, review of which was prevented through happenstance. When that procedure is followed, the rights of all parties are preserved; none is prejudiced by a decision which in the statutory scheme was only preliminary." *Munsingwear*, 340 U.S. at 40.

This Court consistently employs such a disposition for cases which become moot pending a decision on certiorari. *Sivley v. Soler*, 113 S.Ct. 454 (1992); *Yellow Freight System, Inc. v. United States*, 113 S.Ct. 31 (1992); *Dillon v. Alleghany Corp.*, 111 S.Ct. 1383 (1991). The same disposition is utilized for cases which have progressed to later stages of review. For example, in *Stewart v. Southern Railroad Company*, 315 U.S. 784 (1942), this Court vacated its own decision in a case which became moot after the decision had been filed but during the pendency of a petition for rehearing. In such circumstances the Court did not allow its previously entered opinion to remain in place. *Id.* The practice of the Supreme Court is consistently followed elsewhere. *See, e.g., Independent Union of Flight Attendants v. Pan American World Airways, Inc.*, 966 F.2d 457, 459 (9th Cir. 1992) (when case becomes moot before mandate issued, "the appropriate disposition is to vacate the panel's opinion and dismiss the appeal."); *Clarke v. United States*, 915 F.2d 699, 706 (D.C. Cir. 1990) ("The standard practice of both the Supreme Court and the courts of appeals calls for automatic vacatur"); *Bumpus v. Clark*, 702 F.2d 826, 827 (9th Cir. 1983).

Wright, Miller and Cooper go even further, and suggest that vacatur by a court of appeals is appropriate not

only when a case becomes moot prior to issuance of the mandate, but through the time available to the losing party to seek certiorari. Citing the Supreme Court's established policy regarding cases becoming moot pending certiorari (to grant certiorari, vacate the opinion below and dismiss the appeal), they suggest, "It is appropriate for a court of appeals to vacate its own judgment if it is made aware of events that moot the case during the time available to seek certiorari." 13A C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedure* § 3533.10 at 435 (1984).

At the moment the event occurred which rendered this case moot – the improvement of Plaintiff's physical condition on or near February 10, 1993, and her accompanying decision not to go forward with HDC-ABMT under the ICE protocol at Moffitt – the Court of Appeals was deprived of jurisdiction. Mutual was immediately thereafter deprived of the opportunity to litigate the matter to its conclusion. While Mutual did not learn of the facts rendering the case moot until after the panel's decision was issued, and was thus unable to bring those facts to the Eleventh Circuit's attention in advance of its decision, the effect of those facts remains the same. The Eleventh Circuit was without jurisdiction to issue its decision, and Mutual should not suffer prejudice from a jurisdictional inability to litigate the issues presented to a conclusion. Federal courts are constitutionally required to continually address the existence of jurisdiction, and to make an appropriate disposition of the matter in light of jurisdictional issues. Here, the decisions of this Court demand that the panel opinion be vacated and the appeal dismissed, precedent ignored by the Eleventh Circuit when it wrongfully continued to assert jurisdiction over the case.

II. THIS CASE PRESENTS AN IMPORTANT JURISDICTIONAL QUESTION OVER WHICH THE COURT SHOULD EXERCISE ITS SUPERVISORY POWERS.

In this case, the Eleventh Circuit acted notwithstanding the absence of jurisdiction, in direct violation of clear precedent of this Court. A grant of certiorari is necessary and appropriate to correct the Eleventh Circuit's erroneous assertion of jurisdiction over a moot issue. This Court often grants certiorari to correct a court of appeal's wrongful exercise of federal jurisdiction, especially when an appeal is rendered moot by changed circumstances. R. Stern, E. Gressman, S. Shapiro, *Supreme Court Practice*, § 4.15 at 220 (B.N.A. 6th Ed. 1986). As the court of last resort in the federal system, the exercise of this Court's supervisory authority over lower federal courts is especially appropriate to correct a jurisdictional defect.

Here, the Eleventh Circuit exercised jurisdiction in direct conflict with Supreme Court precedent involving (1) concepts of mootness, (2) the impact of mootness in an appeal from an order on a preliminary injunction, (3) the effect of certification under section 1221(b) on a moot appeal, and (4) the proper disposition of a case rendered moot on appeal. To allow such a decision to stand would do violence to the jurisdictional limitations placed upon federal courts by Article III, and to the importance of this Court's establishment of jurisdictional boundaries.

CONCLUSION

Mutual respectfully requests that its Petition for Certiorari be granted, the opinions below vacated, the appeal dismissed, and the case remanded for disposition on the merits.

Respectfully submitted,

MUTUAL OF OMAHA LIFE INSURANCE COMPANY, Petitioner

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September, 1993

APPENDIX
TABLE OF CONTENTS

APPENDIX A

Order Denying Appellee's Motion to Vacate Order and Dismiss Appeal as Moot A1

APPENDIX B

Memorandum and Order Denying Appellee's Petition for Rehearing and Suggestion for Rehearing En Banc, Construed as a Motion for Reconsideration of the June 21, 1993, Order Denying Without Prejudice Appellee's Motion to Vacate Order and Dismiss Appeal as Moot..... B1

APPENDIX C

Order of the Eleventh Circuit on the Preliminary Injunction, 986 F.2d 1379 (11th Cir. 1992) C1

APPENDIX D

Order of the District Court on the Preliminary Injunction, 812 F. Supp. 1193 (N.D.Fla. 1992)..... D1

APPENDIX A

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 92-2904

MARY P. DAHL-EIMERS,

Plaintiff-Appellant,

versus

MUTUAL OF OMAHA LIFE INSURANCE COMPANY,

Defendant-Appellee.

On Appeal from the United States District Court
for the Northern District of Florida

(Filed June 21, 1993)

BEFORE: HATCHETT and BLACK, Circuit Judges, and DYER, Senior Circuit Judge.

BY THE COURT:

Appellee's motion to vacate order (this Court's March 9, 1993 opinion) and dismiss appeal as moot is DENIED without prejudice to the right of the parties to raise the issue before the district court.

APPENDIX B

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 92-2904

MARY P. DAHL-EIMERS,

Plaintiff-Appellant,

versus

MUTUAL OF OMAHA LIFE INSURANCE COMPANY,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Florida

(Filed Aug. 10, 1993)

Before HATCHETT and BLACK, Circuit Judges, and DYER, Senior Circuit Judge.

BY THE COURT:

We are not convinced that this case is moot. We also do not think that *In re Ghandtchi,* 705 F.2d 1315 (11th Cir. 1983), establishes a rule of automatic vacatur under all circumstances. The rationale of *United States v. Munsingwear,* 340 U.S. 104, 39-40, 71 S.Ct. 104, 106-07 (1950), upon which *Ghandtchi* is based, is to clear the path for future relitigation of the issues between the parties and to vacate an order that could not be reviewed, so that the parties are not prejudiced by a preliminary decision. This purpose is not furthered by creating an automatic vacatur

rule. In *Ghandtchi,* vacatur was deemed appropriate. 705 F.2d at 1316. We do not consider vacatur to be appropriate in this case. First, *Munsingwear's* purpose would not be furthered by vacatur. In addition, this Court's jurisdiction under § 1292(b) and its opinion are based on a question of law, not on the underlying facts surrounding the disease. The legal question before this Court has not changed – the contract and its language remains the same. Nowhere in any of the briefs is this Court informed of a modification in the contractual language this Court construed. Section 1292(b) jurisdiction is specifically designed to give ongoing litigation the benefit of accelerated appellate review of controlling legal questions, so that the litigation as a whole may be materially advanced. That purpose has been satisfied and, therefore, Appellee's petition for rehearing and suggestion for rehearing en banc, construed as a motion for reconsideration of the June 21, 1993, order denying without prejudice appellee's motion to vacate order (this Court's March 9, 1993, opinion) and dismiss appeal as moot, is

DENIED.

APPENDIX C

Mary P. DAHL-EIMERS,
Plaintiff-Appellant,

v.

MUTUAL OF OMAHA LIFE INSURANCE COMPANY,
Defendant-Appellee.

No. 92-2904.

United States Court of Appeals,
Eleventh Circuit.

March 9, 1993.

Paul R. Miller, Miles Davis, Miles Davis & Associates, Pensacola, FL, Raymond T. Elligett, Jr., Schropp, Buell & Elligett, P.A., Tampa, FL, for plaintiff-appellant.

Thomas E. Johnson, Baird Holm McEachen, Omaha, NB [sic], for defendant-appellee.

Richard G. Tuttle, Anderson, Kill, Olick & Oshinsky, PC, Philadelphia, PA, amicus curiae.

David M. Caldevilla, L. David de la Parte, John R. Thomas, Tampa, FL, for amicus curiae, Moffitt Cancer Center.

Appeal from the United States District Court for the Northern District of Florida.

Before HATCHETT and BLACK, Circuit Judges, and DYER, Senior Circuit Judge.

BLACK, Circuit Judge:

The issue before this court is whether the district court correctly denied Plaintiff-Appellant Mary P. Dahl-Eimers' application for a preliminary injunction. Dahl-Eimers has advanced breast cancer, and she wants Defendant-Appellee Mutual of Omaha Life Insurance Company to pay for high dose chemotherapy with autologous bone marrow transplant (HDC-ABMT) under their major medical expense insurance contract. Mutual of Omaha refused to provide coverage for HDC-ABMT because the company considers it experimental and therefore not medically necessary. The insurance policy covers only medically necessary services, and under the policy medical services that are considered experimental are not medically necessary.

In Dahl-Eimers' application for a preliminary injunction to enjoin Mutual of Omaha from denying coverage under the policy, the district court ruled that she did not have a substantial likelihood of success on the merits. 812 F.Supp. 1193. The court based its ruling in part on its legal determination that the contract term "experimental" is not ambiguous. As explained below, we conclude that the phrase "considered experimental," standing alone in a major medical insurance policy, is ambiguous as a matter of law, and we reverse the district court's decision.

I. BACKGROUND

Dahl-Eimers has Stage IV metastatic breast cancer, which is considered incurable by traditional cancer treatments, but which may respond to chemotherapy drugs in high doses. High dose chemotherapy, combined with autologous bone marrow transplant, has recently been

shown to be an effective treatment in some breast cancer cases,[1] and Dahl-Eimers' treating physician referred her to the H. Lee Moffitt Cancer Center and Research Institute for HDC-ABMT treatment.

The insurance contract between Mutual of Omaha and Dahl-Eimers provides for reimbursement of expenses incurred for medically necessary services or supplies. A medically necessary service or supply is defined in the contract as one that:

> (a) is appropriate and consistent with the diagnosis in accord with accepted standards of community practice; (b) is not considered experimental; and (c) could not have been omitted without adversely affecting the insured person's condition or the quality of medical care.

Mutual of Omaha refused to pay for HDC-ABMT treatment because it determined that the proposed treatment was not medically necessary and therefore was not covered by the policy.

Before the district court, Dahl-Eimers identified the central issues as being whether the term "experimental" is ambiguous and whether the treatment is experimental. Mutual of Omaha contended that Dahl-Eimers did not meet any of the policy's three criteria for a medically

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[1] HDC-ABMT is an established treatment for cancers characterized by diffuse tumors, such as leukemia or lymphoma. Breast cancer, however, is characterized by solid tumors. The efficacy of HDC-ABMT for breast cancer is discussed in, *e.g.*, *Kulakowski v. Rochester Hospital Service Corp.*, 779 F.Supp. 710 (W.D.N.Y.1991); *White v. Caterpillar, Inc.*, 765 F.Supp. 1418 (W.D.Mo.1991); and *Adams v. Blue Cross/Blue Shield, Inc.*, 757 F.Supp. 661 (D.Md.1991).

necessary service. In its order, the district court focused only on subparagraph (b) of the definition of medically necessary and determined that the critical issue was whether the term "experimental" is ambiguous.

The court held that the term "experimental," as applied to the facts of this case, is not ambiguous. It then held that HDC-ABMT treatment for breast cancer is experimental and therefore not covered by the policy. The district court concluded that Dahl-Eimers did not have a substantial likelihood of prevailing on the merits[2] and denied her application for a preliminary injunction. The court certified that its order involved a controlling question of law as to which there is substantial ground for difference of opinion. 28 U.S.C. § 1292.

On Appeal, Dahl-Eimers argues that the district court erred by focusing on the word "experimental" instead of the phrase "considered experimental." She contends that the insurance contract is ambiguous because it does not define "experimental" and it does not specify who will determine whether a service is considered experimental. She asserts that there are a number of reasonable interpretations about who will make the determination

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[2] For a preliminary injunction to issue, the plaintiff must show that: (1) there is a substantial likelihood the plaintiff will ultimately prevail on the merits, (2) the plaintiff will suffer irreparable injury if the injunction does not issue, (3) the threatened injury to the plaintiff outweighs whatever damage the proposed injunction may cause to the defendant, and (4) the injunction would not be adverse to the public interest. *E.g., Sofarelli v. Pinellas County*, 931 F.2d 718, 723-24 (11th Cir.1991). The district court held that Dahl-Eimers satisfied the last three factors.

whether a particular treatment is experimental. She also argues that HDC-ABMT is no longer considered an experimental treatment for breast cancer.

Mutual of Omaha counters that the alternative interpretations offered by Dahl-Eimers are not reasonable. It recognizes that there are various potential sources which could determine whether a treatment is considered experimental, but claims that the contract would only be ambiguous if the various sources could adopt differing, yet reasonable interpretations of the term. Finally, Mutual of Omaha argues that HDC-ABMT, using the particular combination of drugs proposed for Dahl-Eimers, is experimental treatment for breast cancer.

II. STANDARD OF REVIEW

Questions of law are reviewed de novo. *Salve Regina College v. Russell*, ___ U.S. ___, 111 S.Ct. 1217, 113 L.Ed.2d 190 (1991). Under Florida law, interpretation of an insurance contract, including determination and resolution of ambiguity, is a matter of law. *Sproles v. American States Ins. Co.*, 578 So.2d 482, 484 (Fla. 5th DCA 1991); *Gulf Tampa Drydock Co. v. Great Atl. Ins. Co.*, 757 F.2d 1172, 1174 (11th Cir.1985). The portion of the district court's denial of the preliminary injunction based solely on its legal construction of the insurance contract is likewise a question of law. *See E. Remy Martin & Co. S.A. v. Shaw-Ross Int'l Imports, Inc.*, 756 F.2d 1525, 1529 (11th Cir.1985) (conclusions of law in action on preliminary injunction subject to broad review). The district court's findings of fact are reviewed under the clearly erroneous standard.

Newell v. Prudential Ins. Co., 904 F.2d 644, 649 (11th Cir.1990).

III. DISCUSSION

A. *Applicable Law*

Under Florida law, courts must construe an insurance contract in its entirety, striving to give every provision meaning and effect. *Excelsior Ins. Co. v. Pomona Park Bar & Package Store*, 369 So.2d 938, 941 (Fla.1979). An insurance contract is ambiguous if it is susceptible to two or more reasonable interpretations that can fairly be made. *Herring v. First S. Ins. Co.*, 522 So.2d 1066, 1068 (Fla. 1st DCA 1988); *Ideal Mut. Ins. Co. v. C.D.I. Constr., Inc.*, 640 F.2d 654, 657 (5th Cir. Unit B Mar.1981). When one of these interpretations results in coverage and another results in exclusion, ambiguity exists in the insurance policy. *Weldon v. All Am. Life Ins. Co.*, 605 So.2d 911, 915 (Fla. 2d DCA 1992); *Gulf Tampa Drydock*, 757 F.2d at 1174-75.

Ambiguity also may arise from silence. *Cf. Davis v. Crown Life Ins. Co.*, 696 F.2d 1343, 1346 (11th Cir.1983) (ambiguity resulting from silence in certificate of insurance, which did not include a controlling provision recited in the master policy, treated as an express ambiguity). Further, differing interpretations of the same provision is evidence of ambiguity, *Dimmitt Chevrolet, Inc. v. Southeastern Fidelity Insurance Corp.*, 1992 WL 212008, 17 Fla.L.Weekly S579 (Fla.1992), particularly when a term is not explicitly defined or clarified by the policy. *Grissom v. Commercial Union Ins. Co.*, 610 So.2d 1299 (Fla. 1st DCA 1992).

Courts may not rewrite contracts or add meaning to create an ambiguity. *State Farm Mut. Auto. Ins. Co. v. Pridgen*, 498 So.2d 1245, 1248 (Fla.1986). There must be "a genuine inconsistency, uncertainty, or ambiguity in meaning [that] remains after resort to the ordinary rules of construction." *Excelsior*, 369 So.2d at 942. Further, ambiguity is not invariably present when a contract requires interpretation, *Weldon*, 605 So.2d at 915; *Gulf Tampa Drydock*, 757 F.2d at 1175, and failing to define a term does not create ambiguity per se. *Jefferson Ins. Co. v. Sea World, Inc.*, 586 So.2d 95, 97 (5th DCA 1991). Nevertheless, "[t]he insurer cannot, by failing to define the terms . . . or to include any additional qualifying or exclusionary language, insist upon a narrow, restrictive interpretation of the coverage provided." *National Merchandise Co. v. United States Auto. Assoc.*, 400 So.2d 526, 530 (Fla. 1st DCA 1981). Given these rules of construction, we turn now to the insurance policy before us.

B. *Determination of Ambiguity*

Ordinary rules of construction require us, first, to assess the natural or plain meaning of the policy language. *E.g., Landress Auto Wrecking Co., Inc. v. United States Fidelity & Guaranty Co.*, 696 F.2d 1290, 1292 (11th Cir.1983). We must strive to give meaning to every provision, so we must look at the phrase "considered experimental" to determine its meaning within the policy. The policy does not define the term "experimental." The plain language of subparagraph (b), the provision relied upon by the district court to exclude coverage, does not indicate who will determine whether a proposed treatment is

considered experimental.[3] Further, it also omits standards for how that determination will be made. Thus, the contract phrase "considered experimental," without more, gives rise to a genuine uncertainty about who will determine whether a particular treatment is experimental and how that determination will be made. Indeed, even Mutual of Omaha concedes that there could be more than one source of such a determination. Ambiguity in the contract terms arises from the contract's silence on definitions.

The absence of a definition does not create ambiguity per se, as noted above. Nonetheless, the insurance company cannot then claim the narrow and favorable interpretation that its determination, alone, is controlling. In this case, Mutual of Omaha took upon itself the determination of whether the proposed treatment is considered experimental. While that is a reasonable interpretation of the policy language, it is not the only reasonable interpretation. It would also be reasonable to allow the determination of what is considered experimental to made, for example, by the relevant medical specialists, according to generally accepted standards of community practice, or by a national association.

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[3] In subparagraph (a), the policy explicitly sets forth an applicable standard for determining whether a service is appropriate and consistent with a diagnosis, *i.e.*, "in accord with accepted standards of community practice." Subparagraphs (b) and (c) are both silent on the relevant standards, and the entire provision is silent on who would determine whether a particular medical service fits the criteria.

Mutual of Omaha's interpretation excludes coverage, but other reasonable interpretations may result in coverage. For example, although in its order in this case the district court did not assess whether HDC-ABMT is considered an experimental treatment by the relevant medical specialists, other courts have found that the relevant medical specialists do not consider HDC-ABMT experimental. *E.g., Adams v. Blue Cross/Blue Shield, Inc.*, 757 F.Supp. 661, 663 (D.Md.1991) (at the time Blue Cross denied coverage, Maryland oncologists generally acknowledged HDC-ABMT as accepted medical practice).

The existence of differing interpretations of the term "experimental" provides further evidence of a genuine ambiguity. Some courts[4] have found that ambiguity is cured when the term "experimental" is qualified by specifying who will determine the experimental nature of the treatment or by specifying the standards by which the determination of experimental will be made. For example, in *Fuja v. Benefit Trust Life Insurance Company*, 809 F.Supp. 1333 (N.D.Ill.1992), the insurance contract provided coverage for medically necessary treatment, which was defined as treatment that is, among other criteria, "not deemed to be experimental . . . by any appropriate technological assessment body established by any state or federal government." *Id.* at 1336. The court noted that a

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[4] We have not found any reported Florida or Eleventh Circuit cases construing the term experimental or the phrase considered experimental in medical insurance contracts to determine whether the terms are ambiguous. We recognize that the reported cases which do address the issue are ERISA cases governed primarily by federal statute, but we consider the analytical reasoning instructive on the question of ambiguity.

predecessor version of this criterion had been considered ambiguous, but that the qualifier "deemed . . . by [a] technological [assessment] body" largely removed any ambiguity. *Id.* at 1340 n. 4. The court also noted that the National Cancer Institute, an appropriate technological assessment body under the contract, stated in its literature that "the term[] . . . 'experimental' cannot be simply or unambiguously used to define new cancer therapies." *Id.* at 1340.

Similarly, in *Boland v. King County Medical Blue Shield,* 798 F.Supp. 638, 640 (W.D.Wash.1992), a collective bargaining contract excluded experimental or investigational procedures, which were defined as:

> any services so classified by the National Blue Cross and Blue Shield Association and any service whose use is still under clinical investigation by health professionals or is not generally recognized by the medical profession as tested and accepted medical practice. This exclusion also applies to items requiring Federal Drug Administration or other governmental agency approval if such approval was not granted at the time the service or supply was ordered.

The court determined that the contract unambiguously relied on a third-party classification of what was experimental or investigational, and, because the National Blue Cross and Blue Shield Association had classified the proposed treatment as investigational, granted summary judgment for the insurance company. *Id.* at 646.

Other courts have found that the term "experimental" is ambiguous when it is undefined in medical insurance contracts. For example, in holding that Blue Cross-

Blue Shield's policy excluding experimental procedures was ambiguous, the United States District Court for the Eastern District of Virginia noted that the policy did not define "experimental" and did not explain what evidence would be used to demonstrate whether a particular treatment was experimental. *Pirozzi v. Blue Cross-Blue Shield*, 741 F.Supp. 586, 589-90 (E.D.Va.1990). *See also Nesseim v. Mail Handlers Benefit Plan*, 792 F.Supp. 674 (D.S.D.1992) (granting a preliminary injunction and requiring coverage for HDC-ABMT because the terms of the contract were ambiguous). Indeed, in *Johnson v. District 2 Marine Engineers Beneficial Association*, 857 F.2d 514, 516 (9th Cir. 1988), the court stated that "[i]n the context of the modern medicine, the term 'experimental' seems clearly ambiguous on its face." We agree that, in the context of a major medical insurance policy, the term "experimental," and in this case the phrase "considered experimental," is ambiguous when it is undefined.

IV. CONCLUSION

We need not reach the factual question of whether HDC-ABMT treatment for breast cancer is considered experimental. We hold that the district court erred by concluding that the term "experimental" is not ambiguous. The insurance policy does not clearly specify who will determine whether a treatment is considered experimental or how that determination will be made.

Accordingly, we vacate the district court's order denying Dahl-Eimers' application for a preliminary injunction and remand to the district court to determine

whether there is a substantial likelihood that she will prevail on the merits.

VACATED and REMANDED.

APPENDIX D

Mary P. DAHL-EIMERS, Plaintiff,

v.

MUTUAL OF OMAHA LIFE INSURANCE COMPANY,

Defendant.

No. 92-30254-RV.

United States District Court,
N.D. Florida,
Pensacola Division.

July 29, 1992.

Miles Davis, Pensacola, FL, and Wm. Dennis Brannon, Ft. Walton Beach, FL, for plaintiff.

Thomas E. Johnson, Omaha, NE, Ralph A. Peterson, Beggs & Lane, Pensacola, FL, for defendant.

ORDER AND MEMORANDUM OPINION

VINSON, District Judge.

Plaintiff, Mary P. Dahl-Eimers, initiated this litigation for declaratory judgment, for injunctive relief, and for damages, against defendant, Mutual of Omaha Life Insurance Company. The plaintiff is insured under a policy of major medical expense coverage issued by the defendant. The plaintiff has Stage IV breast cancer, and desires to undergo a procedure identified generally as high dose chemotherapy with autologous bone marrow transplant ("HDC-ABMT"), utilizing three chemotherapy drugs known as Ifosfomide, Carboplatinum, and Etoposide

("I.C.E."). The issue presented is whether the HDC-ABMT treatment utilizing the I.C.E. drugs is "experimental" within the meaning of the policy's coverage.

(1) *The preliminary injunction standard.* In this Circuit, the four requisites for issuance of a preliminary injunction are well known: (a) a substantial likelihood that plaintiff will ultimately prevail on the merits; (b) that plaintiff will suffer irreparable injury unless the injunction issues; (c) that the threatened injury to the movant outweighs whatever damage the proposed injunction may cause to the opposing party; and (d) that the injunction, if issued, would not be adverse to the public interest. *See, e.g., Sofarelli v. Pinellas County,* 931 F.2d 718, 723-24 (11th Cir.1991). This matter was promptly set for hearing on the plaintiff's motion for a preliminary injunction because of the obvious need to deal quickly with the issue. For purposes of the preliminary injunction, only the first element needs to be considered, since the remaining three elements are established by the circumstances of the case.

(2) *The plaintiff's cancer and course of treatment.* Plaintiff is a forty-year-old female who resides in Destin, Florida. Her breast cancer was initially confirmed by biopsy on September 30, 1988. Following a right modified radical mastectomy, plaintiff embarked upon an initial course of chemotherapy and radiation treatments considered as standard or conventional therapy. At the end of that course of treatment, there was no clinical evidence that her disease was still existent. However, in August, 1991, plaintiff developed pain in her right hip and was diagnosed with metastatic disease, for which she was treated with a drug called "Taxol" between September 1991 and

March 1992. The cancer now appears to be in remission, although it is classified as "Stage IV metastatic breast cancer." Stage IV metastatic breast cancer is considered incurable by any known therapy. Plaintiff has now decided to explore the possibility of enrolling in the clinical trial of HDC-ABMT involving I.C.E. at the H. Lee Moffitt Cancer Center and Research Institute at the University of South Florida in Tampa, Florida ("Moffitt").

(3) *The terms of the policy.* Under the major medical expense policy of insurance issued by the defendant, the insuring clause on page 4 specifies that the insurance company will reimburse the insured for "expenses" incurred. The expenses are defined as limited to "medically necessary" services or supplies. In turn, that is defined as follows:

> A "Medically Necessary" service or supply means one which: (a) is appropriate and consistent with a diagnosis in accord with accepted standards of community practice; (b) is not considered experimental; and (c) could not have been omitted without adversely affecting the insured person's condition or the quality of medical care.

The critical term for purposes of this case is "experimental." The plaintiff contends that it is an ambiguous term, while the defendant says that it is not. Under Florida law, construction of the terms of an insurance contract is a question of law to be resolved by the court. *Epstein v. Hartford Casualty Insurance Co.*, 566 So.2d 331, 332-33 (Fla. 1st DCA 1990). Further courts are to give the language within an insurance policy a practical and sensible interpretation in accordance with the natural meaning of the

words employed. Construction of the policy language must be:

> . . . by the rule of reason and the principle that even insurance policies must be given practical, sensible interpretations in accordance with the natural meaning of the words employed. Obviously, the rule that ambiguities must be construed against the insurer applies only when a genuine inconsistency, uncertainty, or ambiguity in meaning remains after resort to ordinary rules of construction; it does not allow courts to rewrite the contracts, adding meaning that is not present, or otherwise reach results contrary to the manifest intention of the parties.
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> *Allstate Insurance Co. v. Shofner*, 573 So.2d 47, 49 (Fla. 1st DCA 1990) (citations omitted).

(4) *The HDC-ABMT treatment.* Among cancer researchers, it is generally believed that higher doses of chemotherapy drugs may result in destruction of a greater portion of the cancer cells. However, since the chemotherapy drugs are extremely toxic, the dosage for each of these drugs is limited by the maximum that the human body can tolerate. A significant limiting factor is that very high doses substantially destroy the bone marrow which, ordinarily, is fatal since the bone marrow provides necessary red blood cells, white blood cells, and platelets.

Thus, a major research effort in recent years has been an attempt to increase the maximum tolerated dosage by means of protecting a small portion of the patient's own ("autologous") bone marrow. A major break through was being able to remove, freeze, and reuse the bone marrow. The first trials of this process, "HDC-ABMT," in cancer

treatment involved patients with "diffuse" tumors such as leukemia or lymphoma. Through a series of laboratory and clinical experiments, researchers were able to determine what specific patients were benefitted by specific drugs or drug combinations at specific dose levels. As a result HDC-ABMT for certain diffuse tumors is now recognized as standard therapy. There is no standard therapy recognized today, however, for a "solid" tumor such as breast cancer among women. Over the past few years, perhaps ten to twenty university-affiliated medical institutions have initiated active research programs for HDC-ABMT treatment of breast cancer. These programs involve a limited number of patients at various stages of the disease, and each program generally involves a testing of a particular combination of drugs at various dosage levels, with and without bone marrow purging. Despite high expectations from these clinical tests, the data available from the experiments conducted to date are inconclusive. The results of approximately 1,000 test patients using about six different combinations of chemotherapy drugs are now known to the medical community. For purposes of this case, it is important to note that there is no known published data for the I.C.E. combination of drugs on breast cancer, for which plaintiff seeks treatment at the Moffitt Center.

(5) *Medical Research Requirements.* The requirements of medical research involving human subjects is regulated by the federal government under regulations promulgated by the Department of Health and Human Services and the Food and Drug Administration. Medical experiments with human subjects are generally known within the profession as "clinical trials." Clinical trials are

divided into "phases" which are defined in terms of the research objective and the methodology. Phase I clinical trials are the earliest stage of the testing of a drug or procedure, and follow test tube and animal research. The primary objective of a Phase I trial in the context of drug testing is to determine the toxicity and maximum tolerated dosage of the substance. Dosages are escalated among groups of patients until a dosage is reached where toxicities prove unacceptable.

In Phase II trials, scientific information is gathered regarding the medical effectiveness or ineffectiveness of the procedure. Phase II trials are designed to attempt to determine whether the experimental procedure produces a biological response such as shrinkage of the tumor, and the extent and duration of that response. Phase II clinical trials are statistically designed to involve the fewest number of research subjects necessary to achieve the statistical reliability of the experiment's results.

Finally, Phase III trials are conducted to attempt to compare the medical result of the experimental therapy to a standard therapy or to no therapy at all, in order to allow for reasonable scientific comparison and test conclusions.

All of these testing procedures are implemented through entities called Institutional Review Boards ("IRBs"). An IRB must be established and maintained by each institution engaged in medical research involving human subjects. Every research project must be submitted to the controlling IRB via a document known as the "protocol." The protocol sets out, *inter alia*, eligibility requirements for subjects, the number of subjects to be

enrolled, and the objective of the research project. Full disclosure is required.

Each participant in a research project is required to be fully informed, and this is done via a specialized document known as the "informed consent" document. The Code of Federal Regulations sets out what must be included in the "informed consent" document.

(6) *The "protocol" document and the "informed consent" document involved in this case.* The protocol document for the Moffitt Cancer Center, for which the plaintiff seeks treatment, is in evidence, as is her informed consent document. As the protocol's title reflects, it is a "Phase I-II study of intensive-dose [I.C.E.] combination chemotherapy." It contemplates dosage levels escalating up to four times the approved dosage limit of Ifosfomide; up to fifteen times the approved dosage of Carboplatin; and up to three and one-half times the approved dosage of Etoposide.

The protocol sets out the purpose of the study in paragraph (2.4): "The present study proposes that the combination of drugs . . . [I.C.E.], which represents a novel multi-agent regimen, followed by autologous bone marrow transplantation, be evaluated in a dose escalation fashion. . . . " A number of types of cancers are to be included within the study, including "metastatic breast cancer responding to therapy." The concluding sentence of paragraph (2.4) reads: "A major goal will be to define the maximum tolerated dose of this combination of drugs."

In the "informed consent" document, the clinical trial participant is required to acknowledge "I understand that

the investigators will be measuring how well my disease responds to the drug as well as any side effects to the drugs on the study." The document sets out that participation as a research subject "is voluntary," and "there is no guarantee that this will be successful." The clinical trial is referred to throughout the document as a "study."

The estimated cost of the plaintiff's participation in the Moffitt Center's clinical trial is approximately $150,000. Since there is apparently no outside funding for this type of clinical research at the Moffitt Center, the participants (or the participants' insurance companies, if applicable) are expected to pay. Naturally, the medical research team members are most interested in getting the appropriate representation of participants into the clinical tests. Therefore, it must be recognized that the testimony and affidavits of such medical personnel have a decided bias in favor of attempting to get the insurance companies to fund this research.

(7) *Analysis.* Both sides have submitted numerous reported court decisions dealing with the question of whether HDC-ABMT is within the scope of coverage of a medical insurance policy. Although some of the reported decisions deal with the subject in such a general fashion as to be completely irrelevant to what I consider to be the critical inquiry, and others are clearly distinguishable because of the different types of cancer involved or the different insurance policy clauses being applied, the cases are about equally divided on the issue.

The inquiry in this case is plainly fact-specific, and must be resolved by applying the term "experimental" to the actual procedure being contemplated by the plaintiff

for her treatment. Within this context, the term "experimental" is not ambiguous. It has a plain and ordinary meaning which can be applied to the circumstances and facts of this case without any conflict. As defined in Webster's Ninth New Collegiate Dictionary (Mariam-[sic]Webster, Inc. 1985), an "experiment" is "an operation carried out under controlled conditions in order to discover an unknown effect or law, to test or establish a hypothesis, or to illustrate a known law." In turn, "experimental" means "relating to or having the characteristics of experiment: TENTATIVE [still in the "experimental" stage]".

Under the facts of this case, the inescapable conclusion is that plaintiff's projected treatment is "experimental." Both the protocol document and the informed consent document associated with the clinical trial at the Moffitt Center leave no doubt about the nature of the study. It involves the testing of three chemotherapy drugs which have not previously been utilized together in the HDC-ABMT regimen. It is clearly an attempt to try to isolate the maximum dosages that can be tolerated among a variety of types of cancers. It sets out a prescribed regimen of dosages that will be applied to all of the study's participants, without regard to any individual characteristics or peculiarities. Under the protocol, each patient "gets the same predetermined treatment, the same dose, the same frequency." [*See* Herberman deposition, p. 108] It is this characteristic of the study for which the plaintiff seeks to be enrolled that easily distinguishes it from any "treatment." Accepted treatment "tends to be an individualized approach," in which the "physician will adjust the dose or on a frequency of administration

based on a variety of situations and their intuition about what would be the optimum treatment for that given patient." [*Id.*] On the other hand, in protocol research, "one needs to standardize as much as possible the treatment amongst all the patients who are entered so that one could compare as much as possible the results from one patient to the next." [*Id.* p. 109-109] Presumably, no treatment could be ethically prescribed for a patient by a physician unless there was some expectation that it was potentially beneficial to the patient. Thus, I reject any purported definitions framed by other courts or experts which attempt to read an ambiguity into the term "experimental" on the basis of whether it benefits a patient. That type of analysis simply is wrong.

(8) *Conclusion.* The parties have submitted an abundance of evidentiary material in connection with this matter, and have also relied upon numerous reported court decisions, as discussed above. However, I do not feel it is necessary to further discuss the evidentiary material or the legal authorities in any detail, for the issue is quite narrow and quite focused. The plaintiff, like approximately 50,000 other breast cancer patients each year, is bravely facing a situation where her alternatives are few, and none are particularly attractive. The clinical study in which she seeks to be enrolled is definitely "experimental" as applied to the I.C.E. combination of chemotherapy drugs for treatment of breast cancer. The insurance policy does not provide coverage for treatment that is "experimental." I am certainly sympathetic to the plaintiff's plight and her rational desire to pursue any path of treatment that holds any promise of success. Yet, in truth, whether the I.C.E. combination of drugs has a

beneficial – or deleterious – effect upon breast cancer that has progressed to Stage IV is simply not known. That is, understandably, why the Moffitt Center desires to enroll the plaintiff in its study. It is equally understandable why the plaintiff, after giving due consideration to all her alternatives, may want to pursue that course of treatment.

It is unfortunate that adequate funding for clinical trials of drugs and treatments for catastrophic illnesses is not available from the federal government. But such funding is quite limited, and is thinly spread among thousands of competing programs involving literally hundreds of various illnesses and diseases. Thoughtful people need to ponder how this problem can be fairly resolved.

Since it does not appear that the plaintiff has substantial likelihood of prevailing on the merits of this case, the motion for a preliminary injunction must be, and is, DENIED.

In accordance with Title 28, United States Code, Section 1292, I certify that this order involves a controlling question of law as to which there is substantial ground for different of opinion, and an immediate appeal may materially advance the ultimate termination of the litigation. Time is also of the essence.